Prioritizing Chemicals under the EU's REACH Regulation

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ENVIRONMENTAL DEFENSE

finding the ways that work

Policy functions affected by prioritization under REACH

- Identifying chemicals of concern
- Facilitating or requiring the reporting and generation of risk-relevant information
- Assessing information to determine hazard / exposure / risk
- Imposing controls to mitigate risk

Identifying and prioritizing chemicals of concern

REACH Prioritization Criteria

Two sets of specific criteria:

- Classification criteria for identifying dangerous substances, covering 16 pchem, health and eco endpoints
- Criteria to identify “substances of very high concern” (SVHCs): CMRs, PBTs, vPvB; catch-all for “equivalent concern”
- Used to: require Registration sooner; require more information; prioritize chemicals for Evaluation, Authorization or Restriction

Dangerous Substance Criteria

Physicochemical Properties	Toxicological Properties
•Explosive •Oxidizing •Extremely flammable •Highly flammable •Flammable	•Very toxic •Toxic •Harmful •Corrosive •Irritant •Sensitization
Specific Effects on Human Health •Carcinogenic substances •Mutagenic substances •Substances toxic to reproduction	•Environmental Effects •Aquatic environment (include biodeg., bioacc.) •Nonaquatic environment

REACH Persistence Criteria

	Persistent	Very Persistent
marine water	$t_{1/2}$ >60 days	$t_{1/2}$ >60 days
fresh- or estuarine water	$t_{1/2}$ >40 days	$t_{1/2}$ >60 days
marine sediment	$t_{1/2}$ >180 days	$t_{1/2}$ >180 days
fresh- or estuarine water sediment	$t_{1/2}$ >120 days	$t_{1/2}$ >180 days
soil	$t_{1/2}$ >120 days	$t_{1/2}$ >180 days

REACH Bioaccumulation Criteria

- Bioaccumulative = BCF >2,000
- Very Bioaccumulative = BCF >5,000

REACH Toxicity Criteria

- Long-term no-observed effect concentration (NOEC) for marine or freshwater organisms <0.01 mg/l, or
- The substance is classified as carcinogenic (category 1 or 2), mutagenic (category 1 or 2), or toxic for reproduction (category 1, 2, or 3), or
- There is other evidence of chronic toxicity (see next slide)

REACH Chronic Toxicity Criteria

- Danger of serious damage to health by prolonged exposure: serious damage (clear functional disturbance or morphological change which has toxicological significance) is likely to be caused by repeated or prolonged exposure by an appropriate route.

REACH Chronic Toxicity Criteria

Classification (Risk Phrase)	"Toxic" (T, R48)	"Harmful" (Xn, R48)
oral, rat (mg/kg/d)	<5	<50
dermal, rat or rabbit (mg/kg/d)	<10	<100
inhalation, rat (mg/L, 6 hr)	<0.025	<0.25

REACH SVHCs

"Substances of equivalent concern"

- Those having endocrine disrupting properties, or those having PBT or vPvB properties that do not meet REACH's criteria but for which there is scientific evidence of probable serious effects to human health or the environment
- Identified on a case-by-case basis

Facilitating or requiring the reporting and generation of risk-relevant information

REACH Registration

- Registration – 4 tiers of data req'ts:
  - 1-10, 10-100, 100-1000, >1000 tonnes/yr
- Data reqts. ↑ with tonnage, hazard
- Existing chemicals: Phase-in over 11 years
  - 2010: >1000 tonnes/yr
  - 2013: 100-1000 tonnes/yr
  - 2018: 1-100 tonnes/yr
  - BUT: CMRs, aquatic toxicants accelerated

REACH Registration

Enhanced Registration requirements:

- Earliest deadline applies to:
  - CMRs at ≥1 tonne/yr
  - Substances very toxic to aquatic organisms at ≥100 tonnes/yr
- Data reqts. ↑ for low-volume substances:
  - that are SVHCs, or
  - that are known / predicted to meet dangerous classification criteria and are used in dispersive applications (e.g., consumer products)

Substances in Articles

Must be registered if it is:

- used at ≥1 tonne/yr/producer, and
- intended to be released, and
- not registered for that use by chemical's mfctr.

If it is a SVHC subject to authorization, its use must be notified if:

- used at ≥1 tonne/yr/producer, and
- present at >0.1% by weight, unless
- exposure can be excluded

Testing under REACH

- All pre-existing data must be submitted
- Only test proposals – not test data – required for higher tiers at Registration
  - Driven by animal welfare concerns
- Latitude to waive higher-tier testing reqts. based on "demonstration of low exposure"
  - Criteria yet to be developed
- Many conditions where test data "may be omitted, replaced with other information, provided at a different stage or adapted in a different way" (see next slide)

Testing under REACH

Alternatives to new testing allowed under REACH:

- Existing data, incl. non-GLP in certain conditions
- Historical human data (epi/occ/clinical/accidents)
- Weight of evidence
- (Q)SARs
- *In vitro* methods
- Categories, read-across approaches
- Testing not technically possible (e.g., unstable, reactive, highly volatile substances – endpoint, route-specific

Assessing information to determine hazard/exposure/risk

REACH Registration

- Registrant conducts assessments – major difference from TSCA/CEPA
- For chems >10 t/yr, must assess:
  - pchem, human and env'tl. hazards
  - whether chemical is PBT or vPvB
- For chemicals with dangerous properties or PBTs or vPvBs, must also:
  - assess exposure
  - characterize risk

REACH Evaluation

- Govt. can evaluate registrations
- Candidate list prioritized based on risk, considering:
  - Hazard (P, B, T properties)
  - Exposure information
  - Aggregate tonnage
  - BUT: No minimum number/pace at which evaluations are to be done

REACH Evaluation

- Evaluation can lead to:
  - Requirement for more info, testing
  - Proposal to identify chemical as "substance of very high concern" that
    - should be subject to authorization
    - is not adequately controlled, should be restricted

Imposing controls to mitigate risk

REACH Authorization

- Candidate list of SVHCs must be developed …
  - PBTs, vPvBs, CMRs, “equivalent concern” substances
- Priority to be given to SVHCs that are:
  - PBTs, in wide dispersive use, or made in high volume
- Involves extensive review/comment/ approval procedures
- BUT: Candidate list is made public – strong market signal

REACH Authorization

- Companies must apply for authorizations, which are for specific use(s)
- Authorization must be granted if substance is “adequately controlled”
- BUT these substances are ineligible:
  - PBTs or vPvBs
  - Those for which it is not possible to determine a threshold of effect and also are Category 1 or 2 CMRs or of equivalent concern

REACH Authorization

- Any substance can be authorized if it is shown that:
  - socio-economic benefits outweigh risks, and
  - no suitable alternative substances or technologies
- All authorizations to be subject to time-limited reviews, set case-by-case

REACH Authorization

- Applicants for authorization must submit:
  - "analysis of alternatives" that must consider their risks and technical and economic feasibility of substitution, and can consider socio-economic factors; and
  - if viable alternative is identified, a substitution plan, timeline.
- Govt must also consider risks, feasibility of alternatives

REACH Authorization

- Authorization entails most of the same elements as "unreasonable risk" under TSCA:
  - consideration of significance of risk and ability to "adequately control" it
  - socio-economic benefits vs. risks and
  - availability of alternatives
- But: Burden is on industry, not govt.

For more information on REACH in relation to US and Canadian chemicals policies, see

Not That Innocent: *A Comparative Analysis of Canadian, European Union and United States Policies on Industrial Chemicals*

www.environmentaldefense.org/chempolicyreport